# ST Monitoring on the Programmer for Implantable Cardioverter Devices

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ABSTRACT

ST Monitoring on the Programmer for Implantable Cardioverter Devices

Sarina Satya

Cardiovascular disease is one of the most prevalent causes of death. However, if cardiovascular disease is identified early and treated appropriately, the mortality in patients with cardiovascular disease can be hugely reduced. For several decades, 12-Lead ECG has been the standard technique used to identify ischemia, and recent studies have shown that intracardiac electrogram has many benefits over external monitoring such as holter. ST Monitoring feature has been added to St. Jude Medical intracardiac cardioverter defibrillators (ICD) to leverage the ECG technology for identifying cardiovascular disease. This algorithm monitors the intracardiac electrogram to detect and report patterns which could be related to ischemic events. This feature is expected to enhance the process of identifying ischemia and infarction, and provides long-term management of the disease.

In order to support the new implantable devices with ST Monitoring capability, the programmer software was updated to support this new feature in the device. This thesis discusses the work on the programmer. Chapter 1 begins with a background of how monitoring technology in an implantable device can benefit the patients facing high risk of myocardial infarction. Chapter 2 states the objective for the work on the programmer. Chapter 3 describes the implementation and the application of this feature. Conclusion and future development are discussed in Chapter 5.

Keywords: Merlin.net, St. Jude Medical, Cardiac Device, ST Monitoring

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# I. INTRODUCTION

Cardiovascular disease is the number one cause of death globally. According to the World Health Organization, this disease claims more than 17 million lives a year, representing 30% of all global deaths [1]. In the United States, there are 1.26 million cases of recurrent coronary attack each year, out of which 37% of the people die within a year [2].

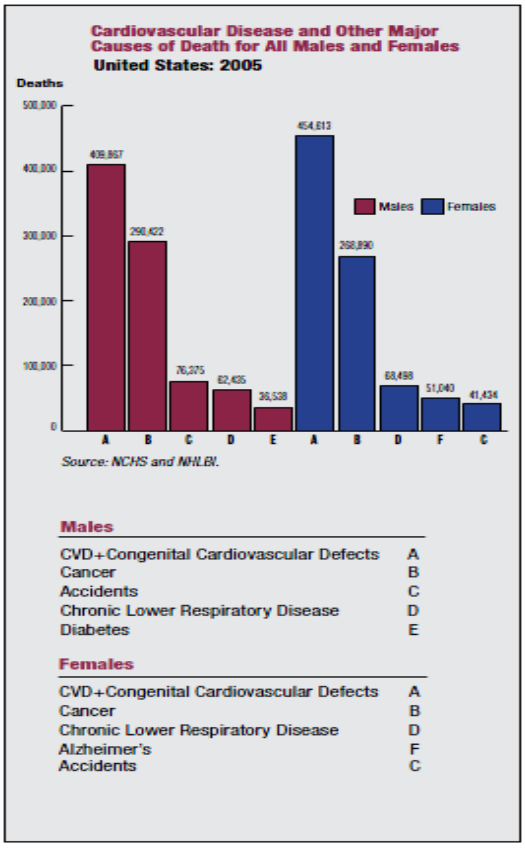


*Figure 1 Heart Disease and Stroke Statistics [3]*

Although cardiovascular disease is prevalent and mortality rate is high, many studies have confirmed that if heart diseases symptoms are identified early, it is possible

to minimize the development of the disease, reduce the risk of heart attack, and increase the mortality in patients with heart disease. However, many patients with heart diseases do not receive timely treatment. During early stage of the disease, many patients do not feel any symptoms for a long time and no treatment or preventive measure is given until the problem develops into a life threatening stage [4]. Also, when patients with acute symptoms are in the hospital, there is still a need to improve the time taken to diagnose the disease which would hugely impact the morbidity and mortality of the patients [11]

Patients who are dependent on implanted device are facing the highest risk of such disease, and EGM patterns have been known to be the best tool to identify their heart anomalies such as ischemia. Therefore, St. Jude Medical collaborated with Angel Medical Systems to co-develop an algorithm to monitor heart beats from an implanted device. This algorithm monitors the intracardiac EGM to detect and report patterns found in the patient that could be indicators of symptoms. These systems indicate severe heart disease which could lead to fatal ventricular fibrillation or infarction. With an implanted device, these patterns can be easily detected even in patients that are asymptomatic. This feature, called ST Monitoring, is expected to be hugely beneficial to these patients, provided that approximately 70 – 90 % of all ischemia detectable with EGM is silent [4].

This chapter will provide a background of the heart and the foundation of using the intracardiac EGM for diagnosing heart diseases. Following that discussion there will be an overview of the benefits of an implantable device that provides chronic monitoring of the ST-Segment.

**Physiology of the heart**

The human heart is a powerful muscular pump. It contracts seventy times per minute on average and pumps about five liters of blood each minute to all organs and tissues. The body needs the oxygen in the blood to carry out normal functions. The circulation of blood also removes waste from those organs and tissues, and delivers deoxygenated blood to the lungs. This is also crucial for the body to carry out normal functions.

The heart has four chambers, two on the left side and two on the right side. The two top chambers are known as the right and left atrium, and the two bottom chambers are the right and left ventricles. The right and the left chambers are separated by a wall called the septum.

The heart is connected to a few large blood vessels which serve as the routes for blood to flow in and out of the heart. There are two major types of blood vessels: arteries and veins. The arteries carry blood from the heart to the body, and the veins carry blood from the rest of the body back to the heart. For example, the aorta artery carries nutrient rich blood away from the heart while the superior vena cava and the inferior vena cava take the blood from the rest of the body into the right atrium. The pulmonary artery carries oxygen depleted blood from the heart to the lung, and the pulmonary veins take blood from the lungs to the left atrium.

In addition, the heart comes with valves that prevent blood from flowing in the wrong direction. These valves are fibrous tissues found between the atria and the ventricles, as well as between the great arteries and at the top of the ventricles. The mitral valve connects the left atrium with the left ventricle, and the tricuspid valve connects the

right atrium with the right ventricle. The aortic valve and the pulmonary valve are found at the base of the corresponding arteries.

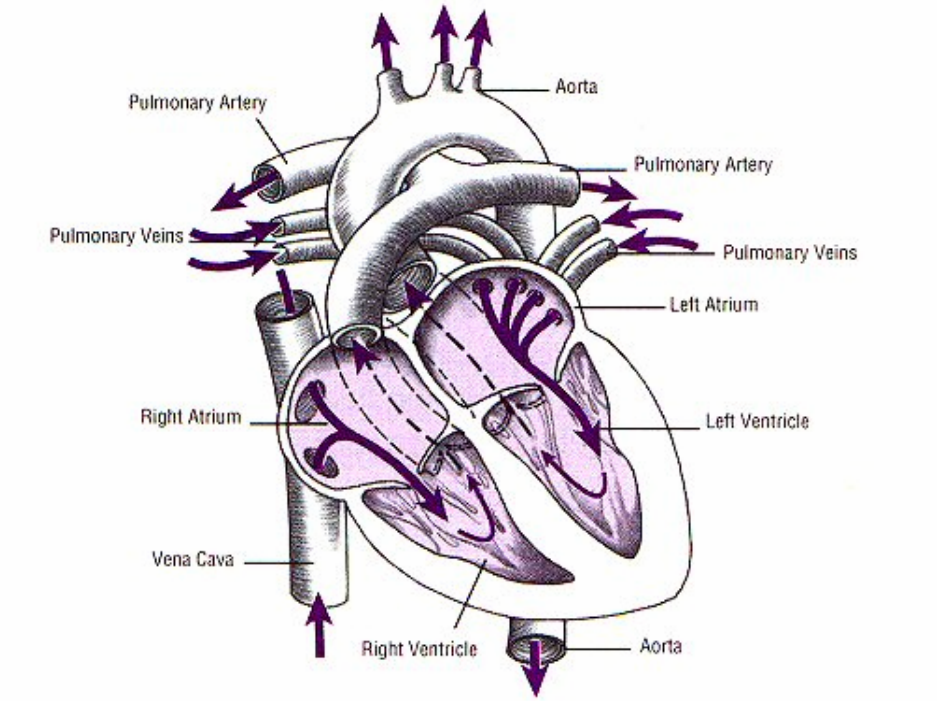


*Figure 2 The Heart [25]*

On the outside, the heart is wrapped around by the pericardium and on the inside it is covered by a smooth lining called the endocardium. The middle layer, which is the thickest layer of the heart, is made up of a special type of muscle called cardiac muscle or myocardium.

As shown in Figure 3 below, the cardiac muscle cells are striated, with muscle fibers parallel to each other branched and joined at various locations resulting in intercalated disks that form a functional network. The pumping action of the heart is the result of coordinated contraction of these cardiac muscles in the heart.

Unlike the skeletal muscles, which contract in response to the stimulus from the nerve terminals attached to them, the cells in the cardiac muscles pass electrical impulses

to their neighbors through special channels called gap-junctions. The heart only needs to be stimulated at one location and the electrical impulses get passed on to the rest of the heart muscle, causing it to contract.

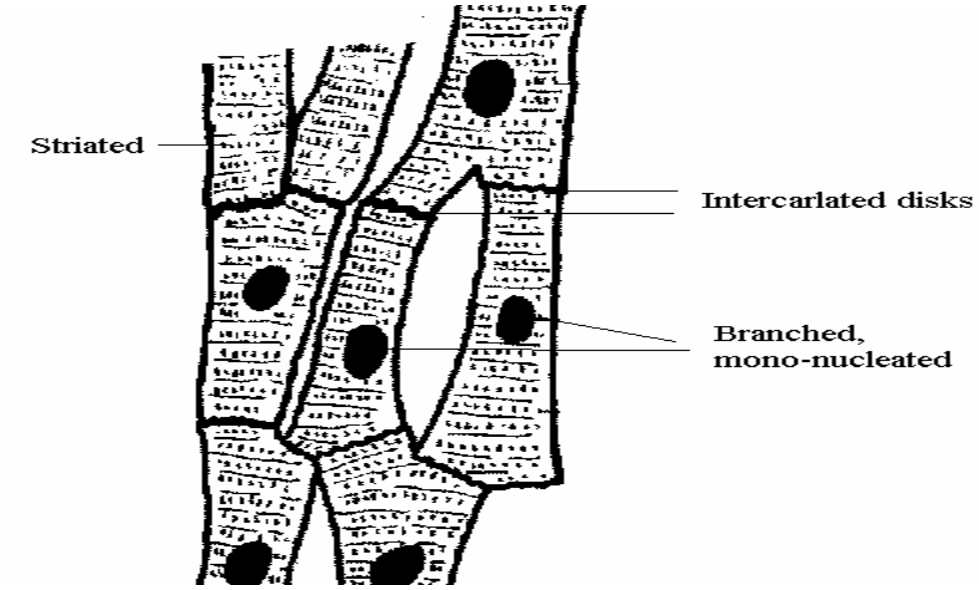


*Figure 3 Cardiac muscle characteristics [25]*

**Action potential in the cardiac muscleF**

Electrical impulses in the heart cause action potential, which is "the change in membrane potential occurring in nerve, muscle, or other excitable tissue when excitation occurs" [17]. Action potential results in the contraction of the cardiac muscle and initiates the pumping action of the heart, and the electrical mechanism associated with action potential provides a way to identify abnormal heart function.

The cell membrane of cardiac muscle is permeable to the ions of elements that are important to the functioning of the heart. The three main elements are potassium, calcium, and sodium. There are "gates", or ion channels, on the cell membrane that control the movement of these charged elements in and out of the cell. As a result of the movement of these ions across the cell membrane, there is a difference in electrical

potential between the inside and outside of a cell, and that is called the membrane potential.

The cells in the cardiac muscle can either be resting or electrically stimulated. A cardiac cell that is not stimulated by an electrical impulse is called a resting cardiac cell. It has less positive charges inside than outside, so the net electrical potential across the cell membrane is negative. When a cardiac cell receives an electrical stimulus from an adjacent cell, it is electrically stimulated. The ion channels open and rapid influx of the sodium ions results in depolarization of the cell and causes the cell to contract.

After depolarization and contraction, the cardiac cells repolarize as positive potassium ions (K+) are pumped out of the cells. The cells return to negative potential. When the cardiac cells are repolarizing, the cells are in refractory and cannot depolarize. The movement of charged ions causes an electrical current which gets transmitted to the adjoining cell and causes it to contract. This depolarization and repolarization continues across a large scale of cardiac muscle contraction leading to the pumping action of the heart's chamber.

The diagram below shows the different phases of action potential that correspond to the voltage changes that are present.

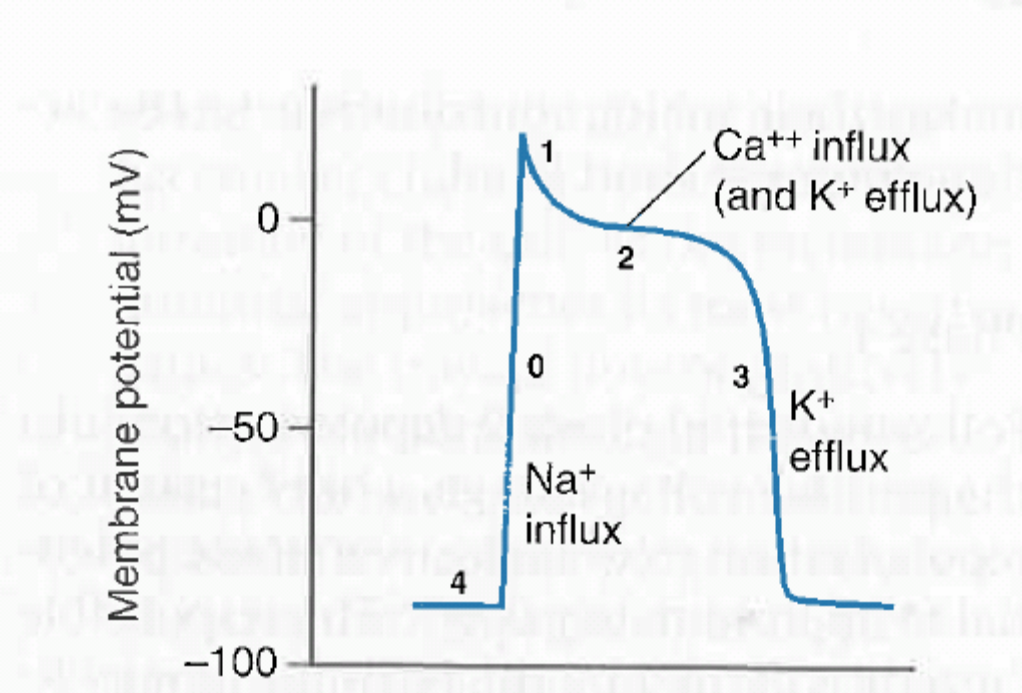


*Figure 4 Cardiac Action Potential Phases [18]*

The cardiac action potential lasts over 300 msec, which is about fifteen times longer than the skeletal muscle action potential, and it consists of five phases. As described above, the phases of the action potential are associated with the movement of the charged ions across the cell membrane. The upstroke in Phase 0 corresponds to rapid depolarization due to a rapid influx of Na+ ions through the fast sodium channels. These channels close abruptly after only a small fraction of a second, and abruptly decrease the permeability of sodium across the cell membrane, and the net outward movement of the potassium ions causes the cross membrane voltage to decline in Phase 1. In Phase 2, the plateau in voltage changes is due to a balance between inward flow of calcium ions and outward flow of potassium ions. The calcium channels close at the end of the plateau, while the potassium channels remain open. The net outward flow of potassium ions

causes a fall in the membrane potential which characterizes the depolarization in Phase 3. The voltage continues to decrease until it reaches the resting membrane potential represented by Phase 4. The cycle repeats when the next electrical stimulus occurs.

**The Cardiac Cycle**

The electrical impulses that are transmitted through the atrium and ventricles cause coordinated contraction of the cardiac muscles and the pumping action of the heart, which is known as the heartbeat. The sequence of events that occurs through the heart from the beginning of one heartbeat to the beginning of the next is known as the cardiac cycle.

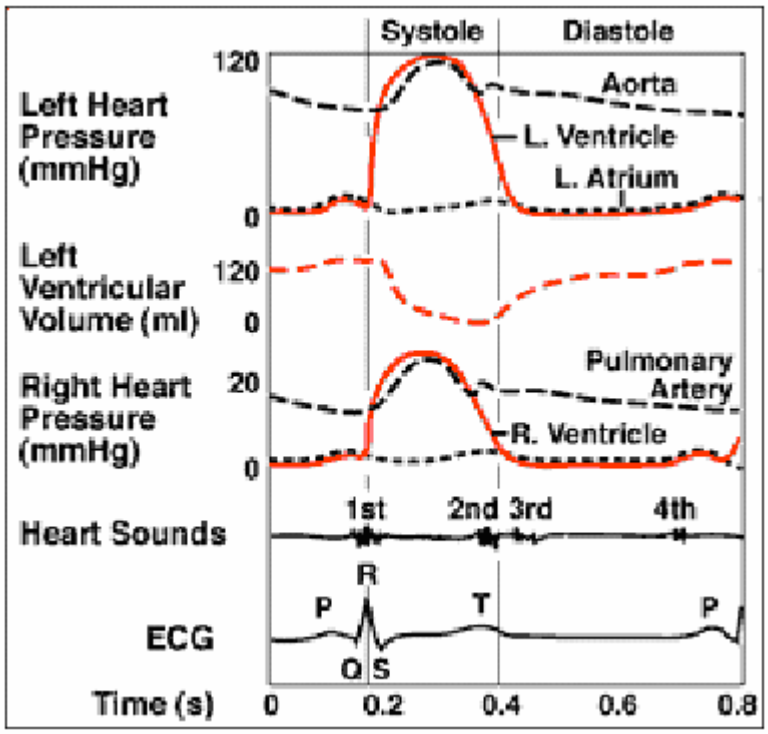


*Figure 5 Cardiac Cycle [19]*

As shown in the diagram above, the cardiac cycle consists of two different stages. During the diastole stage the atria or ventricle relax and fill with blood, while during the systole stage, the muscles of the atria or ventricle contract and pump blood out.

The heart contains pacemaker cells, such as the collection of cells at the sinoatrial node, which can initiate electrical impulses rhythmically. In the beginning of the cycle, the sinoatrial node depolarizes and initiates an action potential and the atria contracts. The action potential travels through the A-V bundle and is delayed for about a small fraction of a second before entering into the ventricles causing the ventricles to contract. As a result, the atria contract ahead of the ventricle and fill the ventricles with blood before ventricular contraction begins.

**Electrocardiogram and the cardiac cycle**

The electrical activity throughout the cardiac cycle can be measured by electrodes placed on the surface of the skin, or by more invasive method such as catheter or implantable pacemaker or an implantable cardioverter defibrillator (ICD). The voltage between pairs of these electrodes, from different directions, is often referred to as the vectors. They are also referred to as leads. Electrocardiogram is the recording and graphical presentation of such electrical activity over time.

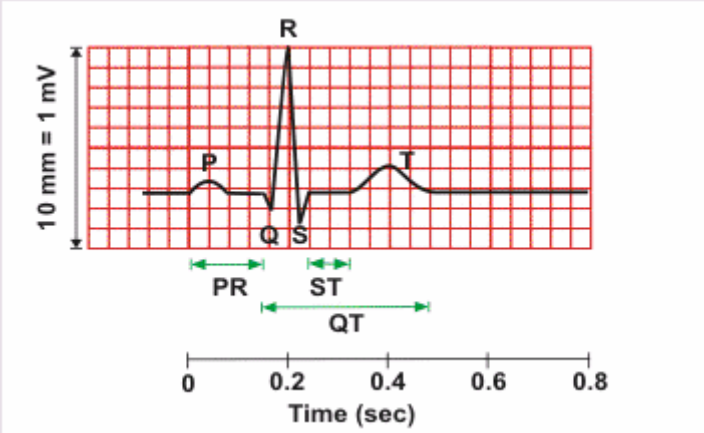


*Figure 6 Normal Electrogram*

The electrogram in the above figure shows the electrical activity of a normal ventricular muscle fiber during normal function. The P, QRS, and T waves correspond to different stages of the cardiac cycle. The P wave represents depolarization of the atria, and the QRS waves represent the depolarization of the ventricles, which is slightly before the onset of ventricular systole. The T wave represents the stage of repolarization of the ventricles, when the ventricles begin to relax.

**Electrocardiogram and cardiac diseases**

Abnormalities or disease of the heart can change the electrical signal conduction pattern and cause abnormal electrical potentials around the heart. In a study done by Kleber and his co-workers [6], transmembrane potentials from pig ventricular cells were recorded before and after occlusion of the left anterior descending artery. This study reported the observation of extracellular potassium activity increased from 4 mM to around 14.7 mM during 15 minutes of ischemia. A few years later, another study also provided similar observation [10]. This study was done on 11 open chest dogs during a 30 min ligation of the left anterior descending coronary artery, and extracellular K+ changes during acute myocardial in the ischemic zone and normal myocardium were

measured. Before coronary ligation, extracellular K+ ranged from 4.0 +/- 0.3 to 4.3 +/- 0.3 mM in the extracellular zone. After ligation, extracellular K+ accumulated in the ischemic reached 9.8 +/- 2.0mM, while the central ischemic zone reached a much higher level (14.4 +/1 4mM). In contrast, no significant changes in K+ occurred in the normal zone throughout the ischemic period. These studies suggested that relative potassium permeability predominates during ischemia, which leads to an increase in extracellular K+, resulting in abnormal membrane potential in the ischemic tissue and membrane depolarization. In addition, it has also been found that an extracellular current, known as current of injury, was found flowing from the injured epicardial border zone towards normal myocardium[22].

The current of injury is the result of the damaged heart tissues being partially or totally depolarized all the time. Excessive extracellular K+ in the injured tissue causes an abnormal potential gradient at the extracellular area between the injured zone and the normal zone. This potential gradient causes a current to flow from the injured areas towards the normally polarized areas. When this current of injury is detected by the electrocardiogram, the ST-segment and the TQ segment on the electrocardiogram will appear to be shifted.

Ischemia is a common cause of current of injury. During ischemia, normal membrane polarization cannot be maintained due to lack of blood supply and other nutrients. As a result of this current of injury, ST-segment elevation is commonly observed on the EGM collected from patients with ischemia.

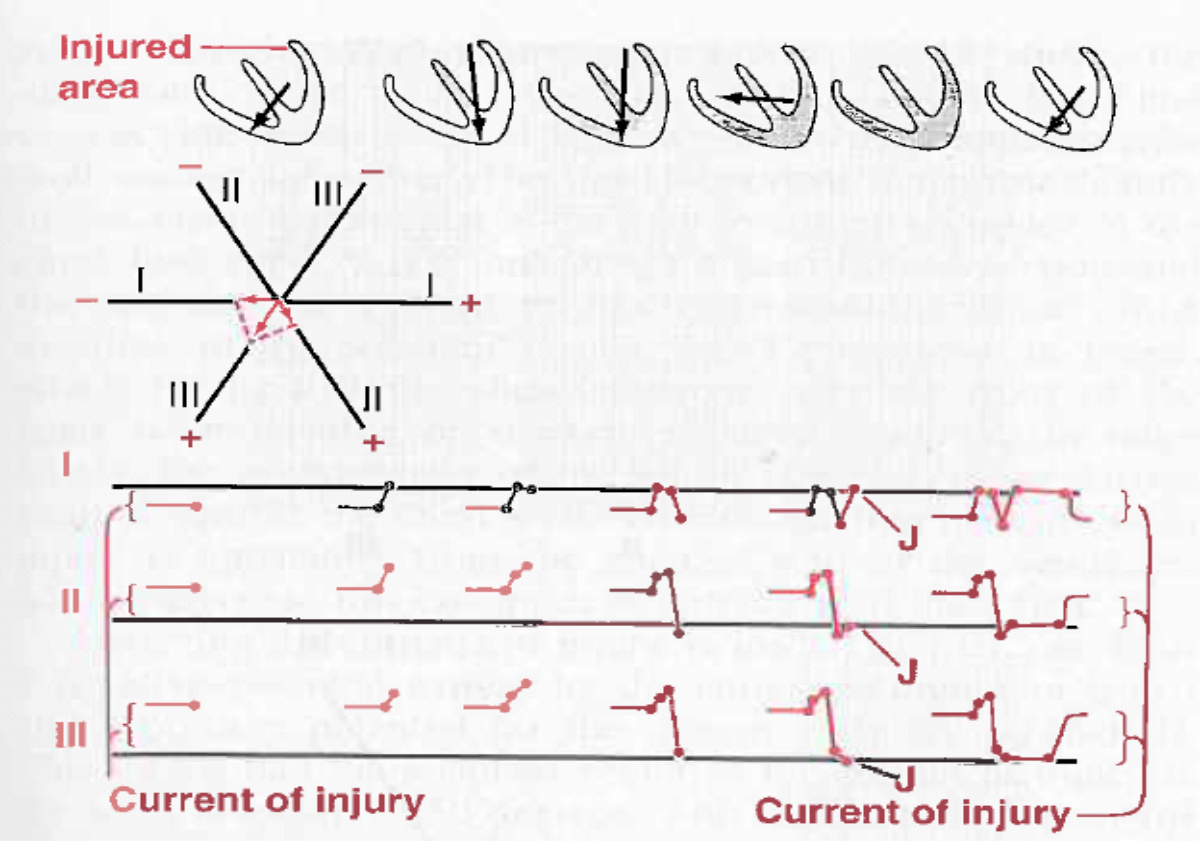


*Figure 7 Current of injury in electrocardiogram [19]*

In addition, Kebler's study also found that there was an increase in extracellular potassium accumulation occurred when heart rate was increased abruptly from 60 to 170 beats/min [6]. The effect of an abrupt change in heart rate was observed during three different time intervals: prior to occlusion, during occlusion, and during reperfusion. In the diagram below, the heart rate was increased abruptly from 60 beats per minute to 170 beats per minute for the times indicated by the bars.

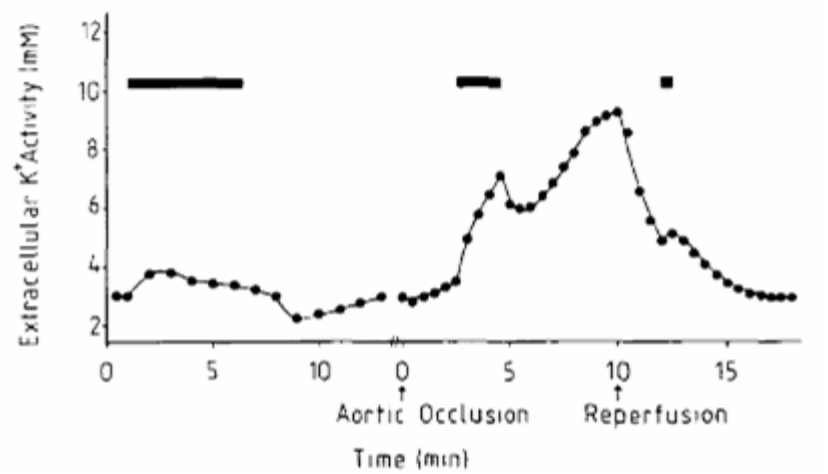


*Figure 8 Extracellular K+ activity [6]*

As shown in the diagram, when the heart rate was increased abruptly from 60 to 170 beats per minute, there was a more pronounced increase in K+ accumulation.

Many studies have been conducted to gain deeper understanding of the mechanisms of the potential difference in cardiac tissues during ischemia. It has been suggested that the cellular loss of potassium is largely due to the opening of ATP-sensitive K+ channels. Blockers for the Katp channels were found to partially prevent action potential shortening and extracellular K+ accumulation. [5, 7, 8, 9]

**ST-segment monitoring and Ischemia Detection**

Ischemia can be symptomatic, asymptomatic, consistent, or unstable. All types of ischemia can be related to the interruption of action potential and delayed or obstructed conduction through the cardiac muscle. Because interruption of the electrical conduction in the cardiac muscle can result in the alteration of ST-segment on the ECG waveform, objective evidences of myocardial ischemia may be obtained from monitoring the ST segment changes

ST-segment elevated ischemia is a common cause of myocardial infarction. Myocardial infarction is commonly classified as STEMI, which is marked by an elevation of the ST segment, or NSTEMI, which is not. A recent report from the National Center for Health Statistics showed that 500,000 out of 896,000 of hospitalizations due to MI are related to a shift in ST-segment [13].

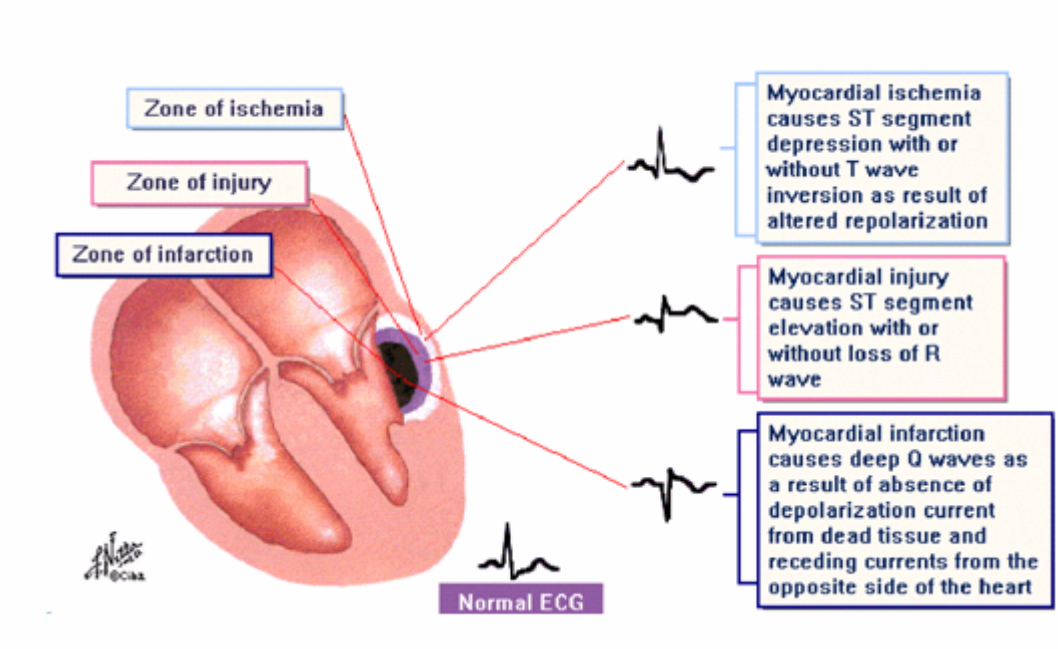


*Figure 9 Possible STEMI electrocardiogram [14]*

12-Lead electrocardiography, vectocardiography, and ambulatory electrocardiogram are common and effective methods for identifying ST-segment elevation. These methods provide important information to guide management and determine prognosis, which are critical in reducing the time to treatment for the patients. [12].

Recent publications have also confirmed the feasibility of using subcutaneous electrodes on implanted devices. Such devices are already being used for detecting other

cardiac events, such as ventricular fibrillation [20]. These studies have also shown that in many ways, implanted devices can be used for the detection of ischemia and provide superior ST-segment monitoring result. Some obvious benefits of using implanted device for ST-segment monitoring are as follows:

(1) For patients who have previous infarction and are at higher risk of recurrent infarction, ST monitoring feature in an implanted device could provide early detection of a serious myocardial infarction and timely notification. The OPTIMAAL trial showed that the majority of sudden deaths (57%) were due to recurrent infarction[21]. The MADIT II study has also shown that implanted defibrillator improves survival for patients with prior myocardial infarction.

(2) Many ICD patients also suffer advance state of cardiac diseases such as coronary artery disease and left bundle-branch block. For these patients, this feature will provide important diagnostic information including chronic intracardiac EGM and events summary information immediately. This information can be used to differentiate ST-segment deviation that results from conditions other than myocardial infarction and avoid unwarranted thrombolytic therapy or emergency angiograph. In the case of acute myocardial infarmtion, such information can shorten time to treatment in case of critical events such as ventricular fibrillation or identify other complicaqtion such as ventricular aneurism. Since the majority of deaths from myocardial infarction occur within the first one to two hours after symptom onset, ACC/AHA 2004 Guidelines for the Management of Patients with ST-elevation Myocardial Infarction recommends to keep ischemic time to within 120 minutes and medical contact to balloon (i.e. treatment with percutaneous coronary intervention) time within 90 minutes.

(3) Patients with coronary artery disease often develop changes over the course of the disease. With implanted device that monitors the ST-segment, changes can be tracked in the ischemic profile of these patients to enable early treatment and reduce future cardiac events.

(4) Monitoring ST-segment changes using holter monitoring is cumbersome. Multiple electrodes and their associated wires need to be managed, and may affect the quality of life for the patients. An implanted device does not require skin electrodes, and external wires. In addition, noise and baseline can be controlled more effectively in an implanted device than holter monitor.

(5) ST-segment monitoring feature in an implanted device may be connected to remote monitoring system. With current state-of-the-art wireless technology, diagnostic data, including related EGM, can be extracted from the implanted device remotely and sent to a remote patient database for storage. The data can be made available to the physician in a timely manner as well as for future reference.

# II. OBJECTIVE

The objective of this project is to update the existing programmer software to extract and interpret the ST Monitoring data from the implanted device, as well as provide an interface for adjusting the feature in the device. The development of the ICD ST Monitoring firmware started in 2007, and the programmer software had to be updated to make the ST Monitoring diagnostics data available to physician.

To accomplish this objective, understanding the requirement and the programmer software thoroughly is critical, because the programmer software was updated according to the requirement. In addition, it is also important to understand the programmer software structure and the techniques used to develop the programmer software. This chapter will first provide a high level discussion of the requirement for the programmer ST monitoring feature, following that this chapter will provide an overview of the existing programmer application software.

**Requirements for the Programmer Application**

- External Instruments Interface Specification (EIIS):

  The interface between the programmer and the implantable device is defined in a set of requirement documents called the External Instruments Interface Specification (EIIS). This document provides information including the following:

  - physical layout of the data in the device
  - mechanism to retrieve the data
  - formulae to interpret the data, and

- Procedures to get the device to perform required functionality.

- Programming Logic Requirements Specification (PLRS)

  Parameters provide meaningful information representing the current state of the device. Most of these parameters also correspond to the information presented on the programmer screen and some of these parameters can be programmed from the programmer screen. The full list of these parameters, and the related display and logical usage of these parameters are found in the requirement called the Programming Logic Requirement Specification (PLRS). This requirement also provides the formulae for correlating these parameters with the information retrieved from the device.

- Use Case: Feature requirement

  The behavior of features supported by the programmer is defined in various Use Case Requirements. There is one corresponding Use Case Requirement for each feature. For example, there is one use case for implanted device connection, a separate use case for managing the programmable parameters, and a separate use case for ST Monitoring, and so forth.

**ST Monitoring Use Case on the programmer**

The programmer is responsible for extracting the ST Monitoring data from the implanted device. This is done during initial interrogation during a patient follow-up session. The data read is interpreted and displayed on the ST Monitoring Workspace of the programer. This workspace also provides the ST Monitoring Setup window which can be used to program the parameters related to this feature. The ST Monitoring workspace provides graphical display of the diagnostics in three different groups: ST

Deviation Trend; ST Episode Log, and ST Histogram Data, and each of these groups present information pertaining to four different heart rate zones.

- ST Monitoring Heart Rate Zones

  ST Monitoring diagnostics data are collected from four different heart rate zones: Resting Heart Rate Zone, Elevated 1 Heart Rate Zone, Elevated 2 Heart Rate Zone, and Elevated 3 Heart Rate Zone. Each zone is defined by a set of maximum and minimum beat-per-minute. The resting zone can be programmed to different values by the user via the programmer while the boundaries for the other heart rate zones are adjusted automatically by the programmer.

- ST Monitoring Deviation Trend

  This information consists of the deviation of the ST segment compared to the isoelectric segment over a period of time. These deviations can be displayed graphically on the programmer as a trend. The deviation trend for all four different heart rate zones are all retrieved from the device. The programmer application converts the raw value to displayable value in “mV” unit. The maximum ST Deviation during the sampling period is also calculated by the programmer.

- ST Monitoring Episode Log

  When an elevation or depression of the ST-segment is detected and the shift exceeds the programmed thresholds, the device will store summary information related to each of the incidences. This information is grouped together and summarized in an ST episode. The information captured includes the following:

- ST Episode Heart Rate at onset (bpm)
- Max ST Shift (%)
- ST Episode Duration (D:H:M:S)
- Stored EGM

The device stores up to 90 ST episodes. However, only the oldest and the most recent 29 episodes are displayed on the programmer screen. In addition, only the oldest and four of the most recent ST episodes will be provided with associated stored EGM. The stored EGMs are collected from a wideband channel with RVtip to Can configuration. Additional processing by the programmer application is required before they are displayed. New VT/VF Episodes within 15 Minutes of any ST Episode are also collected and displayed on the same workspace.

- ST Monitoring Histogram

The ST Histogram contains the total number of beats for each previously defined ST deviation range in each of the four heart rate zones. The histogram data are collected over time, and displayed graphically on the programmer screen during a patient follow-up session.

- ST Monitoring Setup Parameters

ST Monitoring Setup Parameters hold the values used by the device for the detection of ST deviation and ST Episode. These parameters can be programmed by the user to different values from the ST Monitoring workspace. These parameters include the following:

- Isoelectric Start: This parameter determines the starting point for the isoelectric interval for each heart rate zone.
- Isoelectric duration: This parameter determines the time period of the isoelectric interval for each heart rate zone.
- ST Start: This parameter determines the starting point for the ST interval for each heart rate zone.
- ST Duration: This parameter determines the time period of the ST interval for each heart rate zone.
- Positive Threshold: This parameter sets the positive threshold for each heart rate zone.
- Negative Threshold: This parameter sets the negative threshold for each heart rate zone.

➢ ST Monitoring Suggested Thresholds

For the positive and negative threshold values, the ST Monitoring feature provides suggested values for each heart rate zone. The programmer application calculates the values based on the ST Histogram data using an algorithm developed from past clinical studies.

**Programmer Application**

St. Jude Medical Programmer is a computer application that provides clinicians the option to interact with the implantable pulse generators and defibrillator products. The programmer application is responsible for communicating with the devices via a

telemetry wand or other communication technology. User interface with the Programmer includes touch screen, external keyboard, and the console buttons on the programmer.

On the programmer screen, users can view all the data retrieved from the device, including the current settings for all the features, diagnostics data collected over time, and current device status such as the battery longevity. Other actions that can be performed by the user include performing clinical tests on the device and viewing the results, programming parameters to different values, viewing the stored EGMs, and printing reports.

The following section provides an overview of the programmer application structure and various software development techniques used in building this application. The implementation of the ST Monitoring feature is based on the existing architecture of the programmer and similar development techniques.

The programmer application is organized in three layers: User Interface layer, Business Logic layer, and Device Data Layer. Each of these layers consists of one or more sub-systems. For example, the data layer consists of the Device Sub-System, the Communication Sub-System, and the Streaming Data Sub-System. Each of these sub-systems is composed of smaller components. The release of the programmer application consists of all three layers packaged together.

The programmer application development can be classified broadly as framework development and application extension development. The framework consists of java classes that support the function of the application extension, while the application extension consists of java classes which support the use cases. Both framework and application extension are partitioned into the same components and same subsystems as

described above. The sub-systems interface with each other by Application Programmable Interfaces (APIs) or pre-defined events.

At the beginning of each patient follow-up session, each of the sub-systems is responsible for performing any necessary initialization for that sub-system. Similarly, when a patient follow-up session ends, each of the sub-system is responsible for performing any necessary clean-up for that sub system.

- Device Sub System (DSS)

  The DSS is responsible for creating the logical representation of a specific device model and all of its features during a session. It consists of static models that can be used to create the logical representation of the implanted device when one is connected to the other. The DSS is also responsible for reading the raw device data and interpreting the data such that it is meaningful for other sub-systems. In addition, the DSS provides services that trigger various actions in the implanted device. These services include program parameters, read or clear diagnostics data, initiate or terminate clinical tests in the device, and download updated firmware to the device.

- Communication Sub System (DSS)

  The Communication Subsystem (CSS) is a subsystem within the data layer which provides the capability to establish connections with the implantable device. It encapsulates the details of a connection, such as the communication protocol, from other subsystems in the application. CSS creates unique representation of

each connection, and provides all the services needed to establish and control each of the connections.

- Streaming Data System (DSS)

  The Streaming Data Subsystem (SDSS) is another subsystem within the data layer which is responsible for managing and controlling data streams such as the surface EGM, stored EGM, and marker data retrieved from the implanted device. It also provides services to manipulate the data such as heart rate calculation, ECG filtering and annotation, marker decoding, and taking freeze capture of the data stream.

- Graphical User Interface Sub System (GSS)

  The GUI subsystem in the GUI layer is responsible for the look and feel of the programmer screen as well as all the graphical display of the device data. It is also responsible for providing appropriate actions in respond to user interaction on the screen.

- Business Process Sub System and Business Rule Sub System (BPSS and BRSS)

  The Business Process sub system (BPSS) is responsible for representation of application logic. All the business processes collaborate with each other and with the other sub systems. They map the user request from the GUI to appropriate actions in other sub systems, and trigger a GUI update when those actions are complete. The Business Rule sub system is responsible for enforcing logical data

integrity when data is changed. For example, when a user selects a different value for a particular parameter on the GUI, the Business Rule sub-system will check for possible conflicts with the programmed value of all other parameters. If a conflict is found, the GUI sub-system is notified and the conflict will be shown on the screen to inform the user.

- Software language : Java and OOP

  The programmer application is written using the Java programming language and Object Oriented Programming (OOP) technique. OOP is a software development technique which is based on the states and activities of real world objects. The programmer application is built upon the following Java and OOP concepts:

  1. Class: In Java language, a class contains the definition of structure, characteristics, and behavior of a particular thing. It is the blueprint from which an instance of the thing is created.
  2. Instance: An instance is one copy of a class. Different instances of the same class may have different states at any time when an application is running.
  3. Object: An object is an instance of a class.
  4. Thread: A thread is a process, or a single sequential flow of actions within an application. Java supports running multiple threads at the same time within the same application process, which makes the execution of tasks faster and more efficient.

- Software design patterns

The programmer software applied many software design patterns including the following:

1. Type-Object pattern: This is used to separate the objects that hold the information loaded from the pre-defined (or static) model of the implanted device from the objects that hold and process information that are only available during the application run time.
2. Finite State Machine (FSM) pattern: This pattern represents the flow of a process in a finite number of states. Each FSM has a start state and an end state and can be run as a separate thread. Therefore all the FSMs can be executed asynchronously. Within an FSM, the transition from one state to another is triggered by events, and the execution order of the states is dependent on application runtime conditions. Most of the device procedure, such as parameter programming and emergency shock, are implemented using FSM.

# III. IMPLEMENTATION AND RESULTS

In order for the programmer software to support new devices with the ST Monitoring feature, new parameters and new diagnostic models need to be added to the programmer software. In addition, new business logic needs to be added to the programmer software to process the new type of stored EGM related to the ST Monitoring feature. Implementation of a new algorithm for the calculation of the recommended ST-Segment thresholds also needs to be added.

The ST Monitoring project on the programmer was completed in July 2008. The results of this project provided the programmer the capability to turn on this feature in the implanted device when it is first interrogated and the capability to retrieve all of the ST Monitoring diagnostic data from the device during subsequent follow-up sessions. The data retrieved and displayed on the programmer allow the clinician to review the status of the disease. The data can also be printed to a report in PDF format. User interface on the programmer also allows the user to program the parameters to adjust the ST Monitoring algorithm.

As shown in the following screen shot of the programmer, the ST Monitoring workspace contains the display of the ST Deviation Trend, ST Deviation Histogram, and the ST Episode Log summary [15]. The “GOTO Setup Button” will bring up additional windows on which the user can review or program the ST Monitoring parameters.

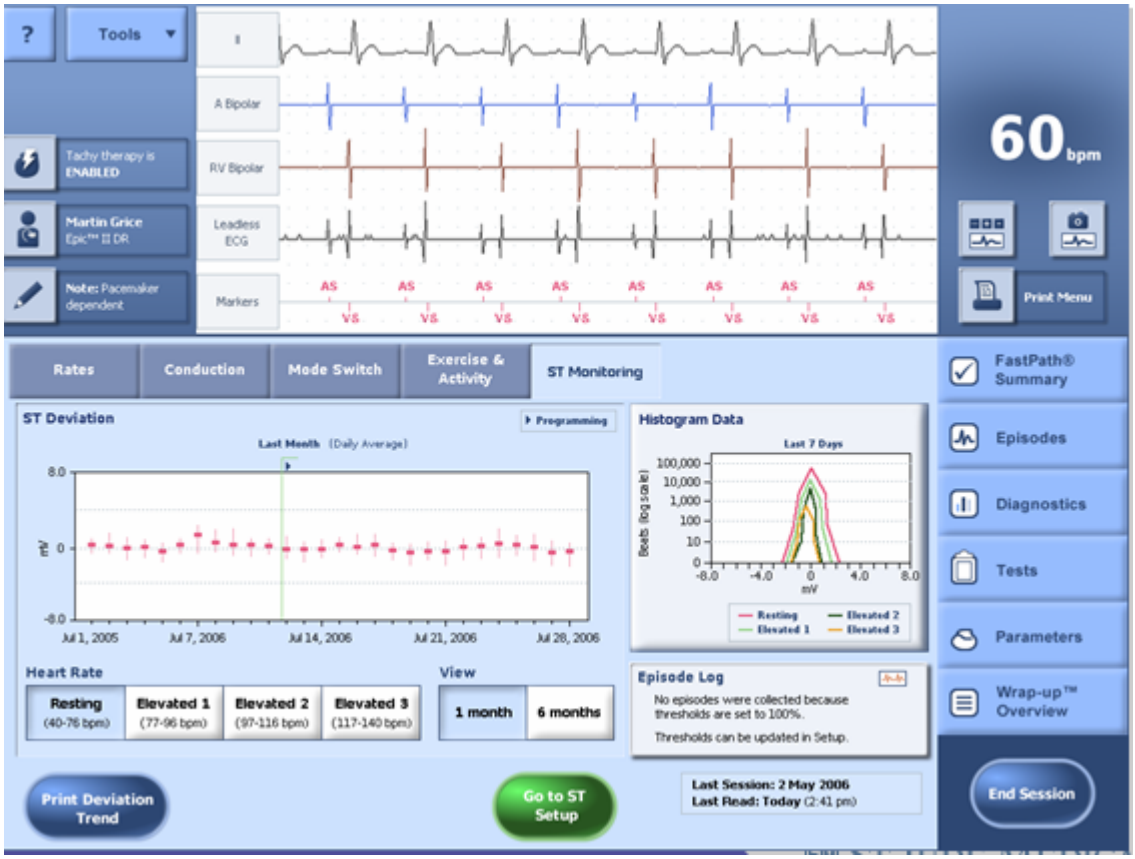


*Figure 10 ST Monitoring Workspace*

**ST Monitoring parameters setup on the programmer**

The programmer screen for the ST monitoring parameters settings are grouped under these four tabs: Isoelectric, ST Interval, Positive Threshold, and Negative Threshold. The user can change these values by touching the parameter panel on the screen. The diagram below shows the screen shot setting up the negative thresholds. Other screen shots for these windows can be found in the APPENDIX.


*Figure 11 Threshold Setup*

When the user selects the parameter panel under any of the four tabs, a separate overlay window will be displayed on which the parameter values can be changed directly. The new values are programmed to the device using the program parameters procedure as discussed in the previous chapter. As shown in the diagram, there is a different set of parameters for each of the heart rate zones.


*Figure 12 Parameter Setup*

**Setup ST Monitoring Heart Rate Zones**

From the ST Monitoring Setup window, if the user selects the heart rate zones panel, the ST Heart Rate Zones overlay window will be displayed. As shown in the diagram, this window only allows the user to change the minimum and maximum heart rates for the resting heart rate zone. The minimum and maximum heart rate values for the other three elevated heart rate zones will be set by the programmer application automatically based on the selected resting zone values.


*Figure 13 Heart Rate Zone Setup*

**Setup ST Monitoring representative beat**

Besides programming the parameters from the overlay windows, the user can also set the values for these parameters using the representative beat which is displayed to the user when the "Select New Beat" button is selected on the ST Monitoring Setup tab.

The representative beat is a reference beat that can be used as the templates for setting other ST Monitoring parameters. It needs to be selected from a patient's stored EGM captured from intrinsic heart beat. If a reference waveform has not been selected, the user is given the option of selecting a waveform from three different sources of stored EGM: ST Baseline SEGM, ST Episode SEGM, or a real time captured and frozen EGM.

The figure below shows the window displaying the ST Baseline SEGMs. The user can select one of the baselines to be the reference waveform from which the representative beat will be selected. The selected SEGM will be shown in the frozen

rhythm panel of the overlay window for beat selection. The selected beat will include 200 ms worth of data before the R-peak and 400 ms worth of data following the R peak.


*Figure 14 Baseline Selection*

**Positive Threshold and Negative threshold**

The positive and negative thresholds are programmable parameters. These are reference values used by the ST Monitoring algorithm for the following purposes:

1. Baseline extraction. During baseline extraction, the ST deviation of the resting zone heart beats are compared to the thresholds, and the baseline is extracted only if the ST deviation is less than 50% of the programmed thresholds.
2. ST-segment analysis. The ST motoring algorithm compare the ST deviation of a set of beats, and if the deviation is more than the thresholds, the current set is classified as an ST set. If three consecutive sets are found to be shifted, an ST

episode is detected. The identified ST episode will be tracked if two consecutive un-shifted ST sets are detected.

**Suggested Thresholds**

Threshold values calculated based on the ST diagnostics data collected in the last seven days are presented to the user along with the programmed values. User can directly select and program these recommended values to be used as the positive and negative thresholds.

The suggested thresholds for the resting heart rate zone are displayed on several of the ST Monitoring setup windows, as shown in the diagram below. User will be provided a reminder to use the suggested thresholds as the as the programmed thresholds as shown in the diagram below.

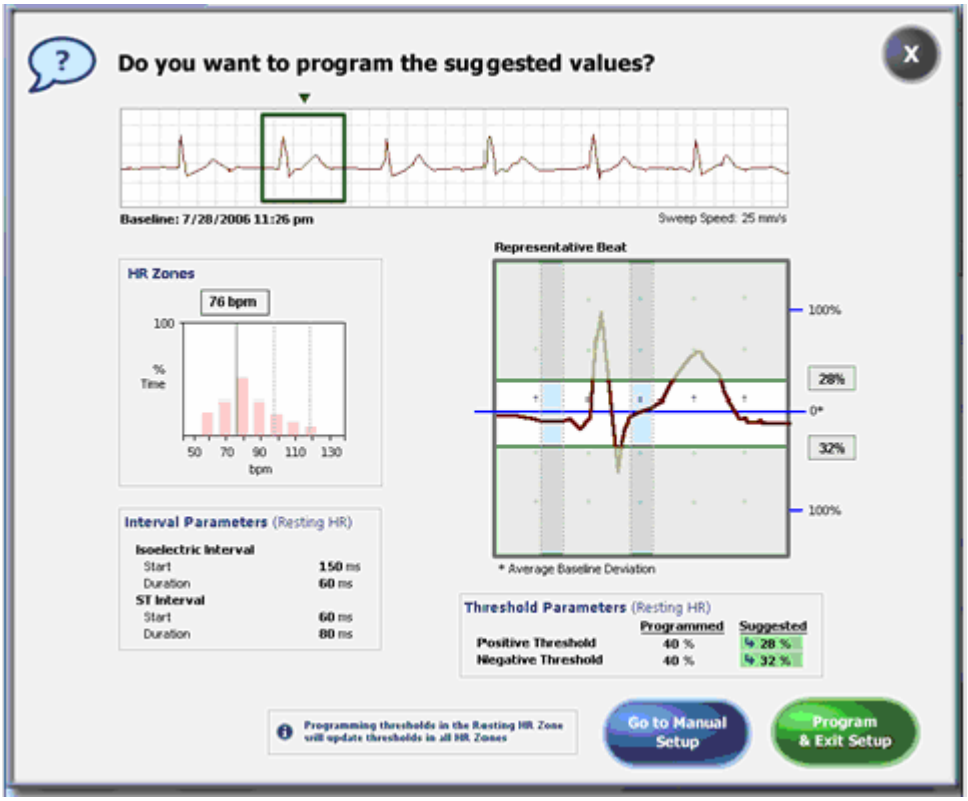


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*Figure 15 Program Suggested Thresholds*

**ST Monitoring diagnostics**

The ST Monitoring diagnostics data are presented in three panels:

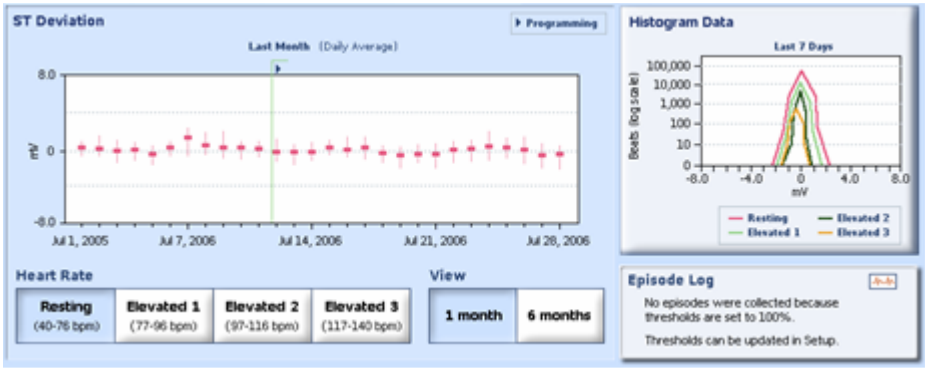


*Figure 16 ST Trend panel*

The ST Deviation panel shows the deviation trend over a time period of either one month or six months. The vertical line shows the minimum and maximum ST Deviation for one day or one week. The small box between the min and max ST Deviation represents the ST deviation value of the histogram bin containing the largest number of analyzed beats per day.

The Histogram Data panel shows the ST histogram line graph. The graph is plotted in “mV” unit on the X-Axis and number of beats in logarithmic scale on the Y-Axis. The data for each heart rate zone is presented in a different color. If the ST Histogram Data panel is selected, an overlay window is provided to the user to view the histogram for any day during the past seven days.


*Figure 17 Histogram Overlay Window*

The Episode log panel contains the summary for the ST Episodes. Detail episode information is shown in a pop up window when the ST Episode Log panel is selected (see

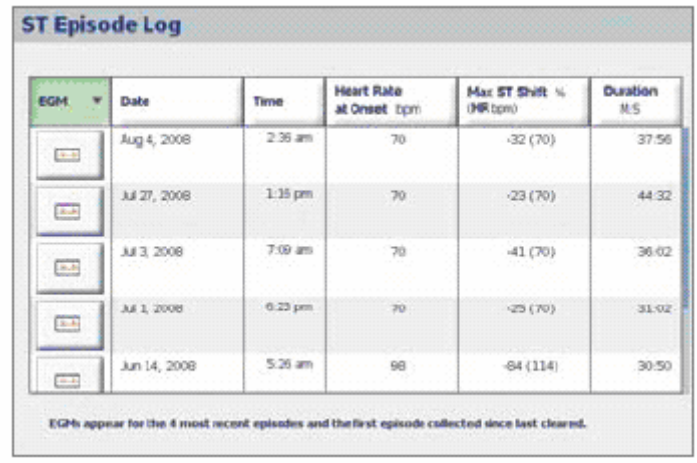


*Figure 18 ST Episode Log*

By selecting the EGM icon on the table will open the ST Stored EGM Overlay. As shown in the overlay window, for each ST Episodes there are three associated Stored EGMs presented along the same time axis: ST Baseline SEGM, Max ST Shift SEGM, and the ST Episode Detection SEGM.

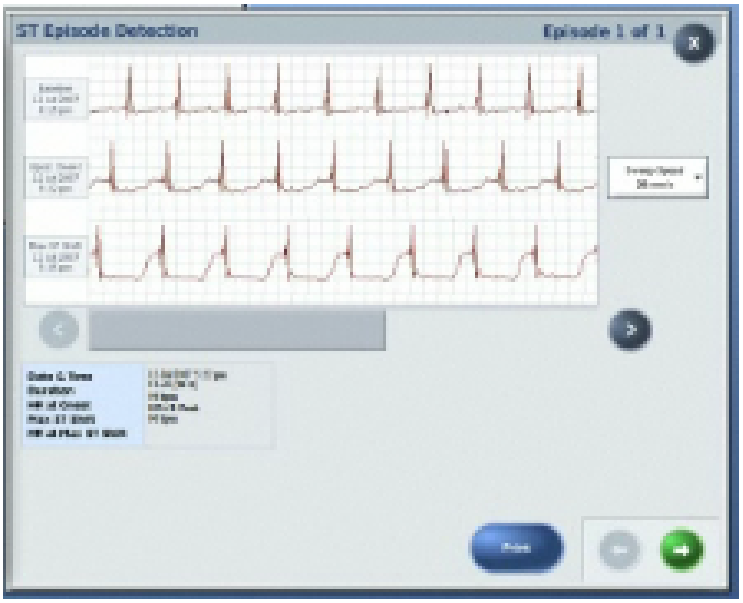


*Figure 19 ST Episode Waveforms*

# V. CONCLUSION

The ICD and the programmer software that support the St. Jude Medical's ST segment monitoring capability was completed in the fourth quarter of 2008 and has been well received in the industry. The programmer application has enabled the retrieval of the ST Monitoring data for the physician and gives physicians more comprehensive ST segment information over time. This continuous ST-segment information provides early detection of potential fatal events and helps to capture cardiac episodes that are transient in nature. As a result, these data can lead to more timely diagnosis and therapy for patients, and possibly improve patient prognosis

As reported by St. Jude Medical in a press release, "The AnalyST ICD is the only implantable device that can provide me with ST segment monitoring reports via high-quality, intracardiac electrograms, as well as additional ST segment diagnostic reports," said Professor Christian Hamm, Ph.D., from the Kerckhoff Klinik who implanted the first AnalyST ICD in Bad Nauheim, Germany. "This device provides me with new and valuable information about my patients' ST segments that is otherwise not available and helps me deliver better and timely care for my patients with arrhythmias and coronary artery disease."

Currently, physicians are also able to review patients' ST segment changes using the remote transmissions from the St. Jude Medical Merlin@home transmitter, which is a wireless remote monitoring system placed in patients' homes. The transmitter sends the ST diagnostics report to Merlin.net, where the data will be stored in a database for an extended period of time. Physicians can retrieve and review the data at anytime from any place where internet service is available. Since the data is stored in a database, physicians

can review the historic data over a long period of time and compare the trend with the latest data retrieved. In addition, the Merlin.net system can be configured to provide notification service to the physician such that whenever critical ST episodes are detected an alert will be sent to the physician via email or phone call.

Currently the ST Monitoring feature is based on the intrinsic rhythm of the patient. The baseline stored EGM, ST-Shift measurement, and the threshold calculations are all based on intrinsic rhythm. To be able to correctly analyze ST-segment shift when paced heart beats are found in the EGM is a highly anticipated breakthrough. Understanding of the EGM patterns for ischemic events which involve ventricular pacing needs to be improved before a reliable algorithm can be made available in an implanted device. Nevertheless, good progress has been made in this area, and many articles have been published with suggested criteria for identifying myocardial infarction when ventricular paced rhythms are part of the waveform.

Better sensing electrodes and lead technology will also be important to the enhancement of using ST-segment for monitoring of heart disease [16]. Increased understanding of the patterns of ST-segment shift will make it possible for implanted devices to provide more information regarding the disease, such as the location of the occluded vessel or the extent of the infracted cardiac muscle. This type of information will be extremely helpful for planning and executing the revascularization procedure.

It is important to continuously find ways for advancing the ST Monitoring algorithm in order to reduce risk wherever possible and contribute to successful outcomes for every patient.

# REFERENCES


1) World Health Organization. <http://www.who.int/entity/cardiovascular_diseases/en/>
2) American Heart Association. <http://www.americanheart.org/presenter.jhtml?identifier=4591>
3) American Heart Association. Heart and Stroke Statistics, 2009.
4) Steven R. Bergmann, MD, PHD, FACC, Kenneth N. Giedd, MD, FACC. "Silent Ischemia, Unsafe at Any Time", Journal of American College of Cardiology, 2003; 42:41-44.
5) JL Hill and LS Gettes. "Effect of acute coronary artery occlusion on local myocardial extracellular K+ activity in swine", Circulation, 1980; 61:768-778.
6) Andre G. Kleber. "Resting Membrand Potential, Extracellular Potassium Activity, and Intracelular Sodium Activity during acute global ischemia in Isolated Perfused Guinea Pig Hearts", Circulation Research. 1983; 52;442-450
7) Ronald A. Li, Michelle Leppo, Takashi Miki, Susumu Seino and Eduardo Marbán. "Mole cular Basis of Electrocardiographic ST-Segment Elevation", Circulation Research, 2000; 87:837-839.
8) Jose M. Di Diego, MD, and Charles Antizelevitch, PhD. "Cellular basis for ST-segment Changes Observed During Ischemia". Journal of Electrocardiology, 2003; 36:Supp. 1-5.
9) Isao Kubota, MD; Michiyasu Yamaki, Takehiko Shibata, Eiichiro Ikeno, Yukio Hosoya, Hitonobu Tomeike. Circulation. "Role of ATP-Sensitive K+ Channel on

ECG ST Segment Elevation During a Bout of Myocardial Ischemia". Circulation. 1993; 88:1845-1851

10) D David, EL Michelson, M Naito, and LS Dreifus. "Extracellular potassium dynamics in the border zone during acute myocardial ischemia in a canine model". Journal of the American College of Cardiology, 1988; 11:422-430.

11) Elizabeth H. Bradley, PHD, Brahmajee K. Nallamothu, MD, MPH, Jeph Herrin, PHD, Henry H. Ting, MD, MBA, Amy F. Stern, MHS, Ingrid M. Nembhard, PHD, Christina T. Yuan, MPH, Jeremy C. Green, BA, Eva Kline-Rogers, MS, RN, Yongfei Wang, MS, Jeptha P. Curtis, MD, Tashonna R. Webster, MPH, MS, Frederick A. Masoudi, MD, MSPH, Gregg C. Fonarow, MD, John E. Brush, JR, MD, Harlan M. Krumholz, MD, SM. "National efforts to improve door-to-balloon time results from the Door-to-Balloon Alliance", Journal of the American College of Cardiology, 2009; 54(25):2423-9.

12) Peter J. Zimetbaum, M.D., and Mark E. Josephson, M.D.. "Use of the Electrocardiogram in Acute Myocardial Infarction", New England Journal of Medicihne, 2003; 348:933-940.

13) Mohammad Reza Movahed, MD, PhD, Radhakrishnan Ramaraj, MD, MHSA,Mehrnoosh Hashemzadeh, PhD, M. Mazen Jamal, MD, MPH, and Mehrtash Hashemzadeh, MS. "Rate of Acute ST-elevation myocardial infarction in the US from 1988 to 2004", American Journal of Cardiology, 2009; 104:5-8.

14) ST Monitoring Overview and Background. St. Jude Medical, 2007.

15) Unity 1.3 Primer, St. Jude Medical, 2007.

16) Auto_Threshold_Guidance. St. Jude Medical Cardiac Rhythm Management Division, 2007.

17) Leonard S. Lilly. Pathophysiology of Heart Disease. 2007.

18) Hall E. John, Guyton C. Arcthor. Textbook of Medical Physiology. 10th edition, 2000.

19) Zhendong Song, BS, Janice Jenkins, PhD, Martin Burke, DO, and Robert Arzbaecher, PhD "The Feasibility of ST-segment monitoring with a sub-cutaneous device", Journal of ElectroCardiography, 2004; 174 – 179.

20) THERES H, STADLER RW, STYLOS L, GLOS M, -ING D, LEUTHOLD T, BAUMANN G, NELSON S, KRUCOFF MW . "Comparison of Electrocardiogram and Intrathoracic Electrogram Signals for Detection of Ischemic ST Segment Changes During Normal Sinus & Ventricular Paced Rhythms", Journal of Cardiovascular Electrophysiology, 2002; 13:990-995.

21) S. Orn, J.G.F. Cleland, M. Romo, J. Kjekshus and K. Dickstein. "Recurrent infarction causes the most deaths following myocardial infarction with left ventricular dysfunction." , American Journal of Medicine, 2005; 118:752-8

22) James MJ, van Capelle FJ, Morsink H et al. "Flow of injury current and patterns of excitation during early ventricular arrhythmias in acute regional myocardial ischemia in isolated porcine and canine hearts. Evidence for two different arrhythmogenic mechanisms", Circulation Research, 1980; 47:151-165.